510(k) Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: June 17, 2004

510(k) number: _____

Applicant Information:
indigo orb, inc.
2355 Calle de Luna
Santa Clara, CA 95054

Contact Person

Name:	Satish Sundar
Phone Number:	(408) 674-1580
Fax Number:	(408) 969-1932

Device Information:

Classification:	Class II
Trade Name:	AutoDetect Syringe
Classification Name:	Piston Syringe
Regulation Number:	21CFR 880.5860
Product Code:	FMF

Device Description:
The AutoDetect Syringe is a spring loaded, loss of resistance syringe used during epidural anesthetic procedures. The device is intended for single-use only.

Intended Use:
The AutoDetect Syringe is intended for use with an epidural needle for the verification of needle tip placement in the epidural space.

Equivalent Device:
The subject device is substantially equivalent in intended use and/or method of operation to the AVID-NIT LOR Syringe (K001731) and the B-D EPILOR LOR Syringe (K925902).

Like the predicate syringes, The AutoDetect Syringe provides a means for detecting entry into the epidural space using the "loss of resistance" technique. All the devices are low friction piston syringes constructed of commonly used polymeric materials, such as polypropylene, silicone and polycarbonate.

The only difference between the AutoDetect Syringe and the identified predicate devices is that the plunger in the AutoDetect Syringe is lightly spring loaded. This convenience feature allows the user to use one hand, as opposed to the two required in the currently used procedure, to identify entry into the epidural space.

Test Results:
Biocompatibility testing to ISO 10993-1, syringe performance testing to ISO 7886-1 and in-vitro and in-vivo simulation testing were performed on the AutoDetect Syringe. Results of testing demonstrate that the AutoDetect Syringe meets its performance specifications and is safe and effective for its intended use.

Summary: Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2004

Indigo Orb, Incorporated
C/O Mr. Morten Simon Christensen
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1655 Scott Boulevard
Santa Clara, California 95050-4169

Re: K041590
Trade/Device Name: AutoDetect Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: June 9, 2004
Received: June 14, 2004

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

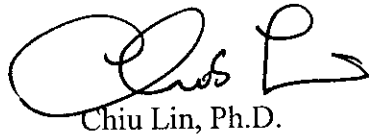
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041590

Indications for Use

510(k) Number (if known): _____

Device Name: **AutoDetect Syringe**

Indications for Use:

The AutoDetect Syringe is intended for use with an epidural needle for the verification of needle tip placement in the epidural space.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K041590